REMARKS

The claims are 1-3, 5, 8, 9 and 11-14. Claims 1 and 12 are in independent form. Favorable reconsideration and allowance of the subject application are respectfully requested in view of the following comments.

REJECTION UNDER 35 U.S.C. § 103

Claims 1-3, 5, 8, 9 and 11-14 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 6,667,050B1 ("*Boissonneault et al.*") in view of U.S. Patent No. 3,619,292 ("*Brouillard et al.*") and further in view of *Olmo et al.* or U.S. Patent No. 6,667,050B1 ("*Boissonneault et al.*") and U.S. Patent No. 4,684,534 ("*Valentine*") in view of *Brouillard et al.* and *Olmo et al.* Applicants respectfully traverse these rejections, in view of the comments set forth below.

Among the noteworthy features of Claim 1, is the inclusion of directly compressible dextrose monohydrate and sucralose.

Applicants have previously explained that the use of directly compressible dextrose monohydrate imparts a smooth, creamy texture and fast melt-away to soft tablets that are designed for chewing or dissolving in the mouth prior to swallowing. Its inclusion in the tablets of the present invention facilitates the manufacture of tablets without the need to include fats and water soluble binders. However, dextrose monohydrate is known to have a relatively high water liability as storage temperatures increase. Thus, unbound water may be present which increases the possibility of a reaction between dextrose and excipients within the tablet. Surprisingly, the inventors have discovered that the inclusion of sucralose is advantageous, since sucralose is a high intensity sweetener that does not react with dextrose in the presence of increased levels of water (see Declaration of Frank Bunick, dated April 7, 2009).

Boissonneault et al., Brouillard et al. and *Valentine* have been discussed previously in Applicants response dated April 22, 2010.

Neither *Boissonneault et al., Brouillard et al.* nor *Valentine* appreciate the difference between dextrose monohydrate and directly compressible dextrose monohydrate. The distinction between the two enables one to manufacture chewable tables without the use of fats and water soluble binders. Moreover, *Boissonneault et al., Brouillard et al.* and/or *Valentine* do not disclose or suggest the understanding that the use of directly compressible dextrose monohydrate comes with the liability of greater quantities of unbound water present at high storage temperatures due to the presence of hydrated dextrose. The unbound water may facilitate a reaction between the dextrose and excipients within the tablet, which may result in browning or discoloration of the tablet. This problem was resolved by the present inventors who realized that the use of sucralose as a high intensity sweetener instead of aspartame, prevented the discoloring and/or browning reaction from occurring.

Olmo et al. discloses the use of EMDEX, a hydrated dextrose that was used as an excipient in a directly compressible tablet formulation. However, like *Boissonneault et al., Brouillard et al.* and/or *Valentine*, *Olmo et al.* also does not recognize the problem created when a hydrated dextrose is used, where there is an increase in unbound water in the tablet at high storage temperatures. Thus, *Olmo et al.* would not recognize that the problem may be avoided by using sucralose as a high intensity sweetener.

Thus, it is respectfully submitted that the proposed combinations of *Boissonneault et al., Brouillard et al.* and *Olmo et al.* or *Valentine, Brouillard et al.* and *Olmo et al.* would not result in a chewable tablet containing a directly compressible dextrose monohydrate and sucralose. The cited references show no appreciation or understanding that the use of

directly compressible dextrose monohydrate may give rise to the presence of unbound water which increases the possibility of a reaction between dextrose and excipients within the tablet. By including sucralose as a high intensity sweetener, the possibility of browning or discoloration due to a reaction with dextrose in the presence of increased levels of water is removed.

As such, Claim 1 is patentable over *Boissonneault et al., Olmo et al., Brouillard et al.* and/or *Valentine* whether considered separately or in the proposed combination.

Claim 12 is similar to Claim 1 and also includes a directly compressible dextrose monohydrate. For at least the reasons stated above for Claim 1, Claim 12 is patentable over *Boissonneault et al., Brouillard et al.* and/or *Valentine*, whether considered separately or in combination.

Claims 2, 3, 5, 8, 9, 11 and 14 depend from Claim 1, and Claim 13 depends from Claim 12. These claims are also believed to be patentable over the cited references, since they depend from a patentable base claim.

CONCLUSION

In view of the foregoing remarks, Applicants respectfully request favorable reconsideration and allowance of the claims in the present application.

Applicants' undersigned attorney may be reached in our office by telephone at (732) 524-1767. All correspondence should continue to be directed to our below listed address.

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